

REMARKS

Claims 1-9, 23, and 25-26 are pending in this application. Claim 1 is amended to clarify the axial rotation of the safety shield and collar with respect to the needle holder and any needle received therein, and claim 23 is amended to clarify the connection between the collar and the holder housing as being adapted for connection with a pivoting safety shield, with the hook arm accommodating the pivotal movement. Basis for these amendment can be found in the original specification and drawings, for example, in paragraphs [0047] and [0048] and FIG. 5. Accordingly, no new matter has been added. In view of these amendments and the remarks presented herein, reconsideration and favorable allowance are respectfully solicited.

Claims 1-4 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 6,298,541 to Newby (hereinafter "Newby"). Also, claims 1-6 and 9 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 4,982,842 to Hollister (hereinafter "Hollister"). Further, claim 8 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Hollister in view of U.S. Patent No. 6,077,253 to Cosme (hereinafter "Cosme"). Still further, claims 7 and 23-26 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Newby in view of U.S. Patent No. 5,197,954 to Cameron (hereinafter "Cameron"). Each of these rejections is respectfully traversed for the reasons set forth herein.

Rejection Under 35 U.S.C. § 102(b) - Newby

As clearly set forth in the claim 1, the holder assembly includes a safety shield and a collar, both of which are axially rotatable with respect to the holder housing about axis of the holder housing, such that the safety shield and the collar can be radially rotated to a desired position around the axis without the axial movement of the collar along the axis. In this manner, when in use with a needle, the safety shield can be rotated, about the holder and therefore about the needle attached thereto, so as to provide an unobstructed view of the needle, without the safety shield being in the way.

Applicant submits that Newby fails to disclose or suggest that the safety shield and collar are axially rotatable with respect to the holder housing about an axis of the holder

housing without axial movement of the collar along the axis of the holder housing, let alone with respect to a needle received within the needle holder, as in claim 1. Newby recites in Col. 6, lines 18-22, that “needle 40 is connected to hub 60 and sealed with adhesive”, and that “hub 60 is joined with collar 90 by ultra-sonic welding techniques or any other bonding techniques.” Accordingly, the needle 40, hub 60 and collar 90 of Newby are bonded together in a fixed position. Newby further recites in Col. 6, lines 43-45, “in use, as shown in FIGS. 7-15, the non-patient needle shield is removed and then a needle holder is screwed onto the hub (60) of the needle.” As shown in FIG. 2, and recited in Col. 5, lines 13-16, of Newby, “threaded end 64 (of hub 60) comprises male threads 80 for mounting the hub on a conventional needle holder.” Accordingly, as shown in FIG. 2 of Newby, the bonded hub 60 and collar 90 with attached shield 140 are screwed together with the needle holder by a threaded engagement. Although the collar 90 can be rotated with respect to the needle holder during the screw-in process of the engaging threads, this rotational screw-in movement **requires** axial advancement of the collar with respect to the needle holder in order for the hub to be attached to the needle holder. As is well known in the art, threaded engagements require axial movement during rotation.

In order to anticipate a claim pursuant to 35 U.S.C. § 102, the reference must teach every element of the claim. See MPEP 2131. Applicant submits that the Examiner has failed to consider the entire recitation of claim 1 in rejecting claims 1-4 under 35 U.S.C. § 102(b) in view of Newby. Specifically, the Examiner has not set forth any indication as to how Newby discloses a safety shield and collar which are radially rotatable to a desired position about the axis without axial movement of the collar along the axis of the needle holder, as recited in previously amended claim 1.

The “Response to Arguments” portion of the Office Action alleges that FIG. 7 of Newby depicts rotation of the collar with respect to the needle housing without axial movement. However, the same assembly shown in FIG. 7 is shown in the exploded view of FIG. 10 of Newby, in which the collar 90 is fixed to the hub 60, which further includes a threaded portion 64 for threaded engagement with the needle holder. FIG. 7 of Newby fails to depict a collar and shield that can be radially rotatable about the axis of the holder housing without axial movement of the collar with respect to the holder housing, and the Action fails in any way to demonstrate where Newby discloses such a feature. Moreover, amended claim 1 clarifies that the collar and

safety shield are axially rotatable with respect to any needle attached to the needle holder. Newby fails to teach such a feature. Accordingly, Applicant submits that Newby does not disclose or suggest that “the safety shield and the collar can be radially rotated to a desired position around a needle received within the needle receiving port and around the axis of the holder housing without axial movement of the collar along the axis, as recited in claim 1.

Applicant submits that independent claim 1, and dependent claims 2-9 depending directly or indirectly therefrom, are patentable over Newby. Reconsideration and withdrawal of the rejection based on Newby is therefore respectfully requested.

Rejection Under 35 U.S.C. § 103(a) – Hollister

Hollister also fails to disclose or suggest an assembly wherein the safety shield and the collar are rotatable with respect to the holder housing about an axis of the holder housing, such that the safety shield and the collar can be radially rotated to a desired position around a needle received within the needle receiving port and around the axis of the holder housing, without axial movement of the collar along the axis.

In fact, the Examiner has acknowledged that “Hollister does not expressly disclose an annular skirt, a safety shield and a collar; wherein the safety shield and a collar can be radially rotated to a desired position around the axis without the axial movement of the collar along the axis.” The Examiner, however, asserts that it would have been obvious to one of ordinary skill in the art to provide a device similar to that of Hollister as shown in Figure 4, with a safety shield and a collar that can be radially rotated to a desired position around the axis without the axial movement of the collar along the axis, as disclosed in Figure 3 of Hollister because such a modification is a design choice.

Hollister merely discloses a conventional luer slip-fit engagement between a needle holder and a shieldable needle assembly. The disclosure of Hollister in Col. 6, lines 17-20 recites that “for the FIG. 3 illustration, assuming that the safety adapter embodiment shown in FIG. 1A is used, the user needs only to slip-fittedly insert male luer 62 into female luer 2b of base 2 for mating.” However, as recited in Col. 4, lines 17-19, of Hollister, “collar 6, although not shown as such in FIG. 1A, in practice, is internally threaded, as shown in FIG. 2A.” Further, with respect to section 2b of the apparatus shown in Figure 3 of Hollister, and as recited in Col.

4, lines 25-28, "at the distal end of hub 16 is, for this embodiment, a circumferential extension 18, extending orthogonally to the longitudinal length of base 2, for mating with the internal threads of a syringe."

Accordingly, in the embodiment of Hollister as shown in Figure 3, both portions 2a and 2b are fitted with threads for threaded mating engagement. As discussed above, all threaded engagements require axial movement during rotation. Therefore, none of the embodiments of Hollister teach or suggest that the safety shield and the collar can be radially rotated to a desired position around the axis without the axial movement of the collar along the axis, as recited in Applicant's previously amended claim 1. Even if the embodiment as shown in Figure 3 of Hollister was combined with the embodiment as shown in Figure 4 of Hollister, the combination would not teach or suggest Applicant's claim 1.

Still further, Hollister does not disclose or suggest any axial rotation of a safety shield or a collar with respect to the needle. Instead, in Hollister, the needle is fixed with the hub and the shield to form an assembly which is attached to the needle holder. In fact, Hollister suggests preventing any relative movement of the shield and the needle, which is entirely contrary to the rotational movement of the shield about the axis, as in the claimed invention.

The Examiner opines in the Office Action that such a feature is merely a design choice, and that the Applicant has not disclosed that having a safety shield and a collar that can be radially rotated to a desired position around the axis without the axial movement of the collar along the axis provides an advantage, is used for a particular problem, or solves a stated problem. Applicant respectfully disagrees. Such a feature is not merely a design choice or simple design modification. In fact, the Abstract of the application clearly recites:

The safety shield is pivotably attached to the collar...The collar and attached safety shield may thus be rotating about the holder housing and an attached needle assembly, thereby allowing a user to freely position the safety shield during needle insertion and preventing the dislocation of the safety shield from the holder housing. (Emphasis added)

Further, the specification recites at page 4, lines 11-14:

With proper molding, the friction between the protrusion of the collar and the groove of the holder housing's annular skirt can be made so that force must be applied to rotate the collar and the safety shield. The shield thus can be set in various positions of angularity during venipuncture. (Emphasis added)

Accordingly, during a medical procedure in which access to the interior of a patient's vasculature is required, an advantage of the presently claimed invention is to allow the safety shield to be rotated to a desired position, i.e., removed from the sightline of the patient puncture site.

Applicant submits that independent claim 1, and dependent claims 2-6 and 9 which depend directly or indirectly therefrom, are patentable over Hollister. Reconsideration and withdrawal of the rejection of claims 1-6 and 9 is therefore respectfully requested.

Rejection Under 35 U.S.C. § 103(a) – Hollister and Cosme

Claim 8 stands rejected as allegedly being unpatentable over Hollister in view Cosme. Claim 8 depends directly from claim 1, and further recites that the collar has one or more slits defined in a rearward annular collar section. As noted, however, Hollister, does not teach or suggest a holder assembly in which the safety shield and the collar can be radially rotated to a desired position around the needle and around the axis of the needle holder without axial movement of the collar along the axis, as recited in independent claim 1. Furthermore, Cosme fails to disclose, teach or suggest a holder assembly in which the safety shield and the collar can be radially rotated to a desired position around the axis without the axial movement of the collar along the axis, as recited in independent claim 1.

Applicant submits herein that neither Hollister, nor Cosme, nor the combination of Hollister and Cosme teach or suggest this feature. Accordingly, for the reasons previously stated herein, Applicant submits that claim 8 is patentable over the combination of Hollister and Cosme. Reconsideration and withdrawal of the rejection of claim 8 is respectfully requested.

Rejection Under 35 U.S.C. § 103(a) – Newby and Cameron

Claims 7 and 23-26 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Newby in view of U.S. Patent No. 5,197,954 to Cameron (hereinafter “Cameron”).

Claim 7 depends indirectly from independent claim 1. The Examiner has failed to provide any indication that Newby or Cameron teach or suggest a holder assembly in which the safety shield and the collar can be radially rotated to a desired position around the axis of the needle holder and around a needle held by the needle holder without the axial movement of the collar along the axis of the needle holder, as recited in independent claim 1. Applicant submits herein that neither Newby, nor Cameron, whether considered alone or in combination, teach or suggest this feature. In fact, the safety shield in Cameron is not in any way axially rotatable with respect to the needle holder, let alone in a manner without axial movement of a collar with respect to the needle holder. Accordingly, for the reasons previously stated herein, Applicant submits that claim 7 is patentable over the combination of Newby and Cameron.

Moreover, independent claim 23 recites, in relevant part, a needle holder with an annular skirt and a collar which attaches to the forward end of the holder housing, with the collar adapted for connection with a pivoting safety shield and having a hook arm for accommodating a pivotal connection of the safety shield, with the annular skirt of the needle holder abutting the hook arm when the holder housing and the collar are in an attached position. Neither Newby or Cameron, whether considered alone or in combination, disclose or suggest such an arrangement.

Newby fails to disclose or suggest an annular skirt extending from the needle holder that abuts a hook arm of a collar attached to the front end of the needle holder. Such a feature is disclosed in the specification at paragraph [0048] as providing structure for pivoting element of the shield to prevent disengagement thereof, and to prevent removal of the shield from the assembly. Newby does not suggest any arrangement whereby a skirt of the needle holder abuts a hook arm of the collar.

Moreover, Cameron fails to add anything to these deficient teachings. Cameron merely teaches a hypodermic syringe having a folding needle, in which a needle hub and a hypodermic needle are pivotably connected to a syringe barrel and retained in position by an extension arm. Contrary to the Examiner’s assertions, the “collar” 72 of Cameron does not

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include the "hook arm" 84. Instead, in Cameron, boss 72 holds the needle to the needle holder through hook 84, which is a part of the needle holder, not a separate collar. Moreover, the hook 84 of Cameron does not accommodate the pivotal connection of the safety shield as required by claim 23.

Accordingly, Applicant submits that independent claim 23, and claims 25-26 depending directly or indirectly therefrom, are patentable over the combination of Newby and Cameron. Reconsideration and withdrawal of the rejection of claims 7, 23 and 25-26 is therefore respectfully requested.

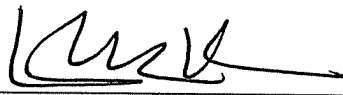
Summary

In view of the above remarks, it is apparent that none of the references disclose or suggest a needle device as set forth in the claims. Accordingly, the present application is deemed to be in condition for allowance. Reconsideration and withdrawal of the rejections and favorable allowance of the application are therefore respectfully solicited.

Should the Examiner have any questions regarding any of this information, the Examiner is invited to contact Applicant's undersigned representative by telephone at (412) 471-8815.

Respectfully submitted,

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